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10/590,382

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Juha Telimaa

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EXAMINER

SHABMAN, MARK A

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/590,382 | Applicant(s) TELIMAA ET AL. | |
| | Examiner MARK SHABMAN | Art Unit 2856 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments, see page 13 lines 5-17, filed 18 October 2008, with respect to the rejection(s) of claim(s) 10, 10, 18 and 21 under 35 USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Kriz.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 17, 18 and 21 recite the limitation "the calibration resolution" in lines 16, 16, 15, and 16 respectively. There is insufficient antecedent basis for this limitation in the claims as the calibration resolution has not been previously disclosed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kriz US PG Pub 2002/0005075 A1 (hereinafter referred to as Kriz).

Regarding **claim 10**, Kriz discloses a hand-held pipette comprising a calibration system. Figure 2 shows a block diagram of the system comprising a "control system" 46, a "user interface" 32, and an electronic display 35 in which volumes are shown. The system comprises a motor driven piston for controlling aspiration or dispensing of the pipette (paragraph [0019] and figures 1 and 2). The pipette further comprises a method of calibration of the system which is described in detail in paragraphs [0025]-[0032]. During calibration, a "real volume obtained with an indicated volume" is input to the system and is adjusted to the desired target. The volume is then measured by the system and a calibration factor is set based on the input values. The process of calibration is used for future readings, thus the calibration factor would be stored in the memory of the system as claimed. Paragraph [0033] describes the adjustment of the piston/motor assembly during the calibration process to correct for the error in the readings of the pipette, thus corresponding to the real dosing volume. The apparatus of Kriz does not explicitly disclose a calibration resolution of less than 0.05%, however, as the structural limitations of the claim are met by the Kriz reference, the reference reads on the claim. It is noted however that as the calibration resolution is a function of the maximum dosing volume of the pipette, by enlarging the capacity of the pipette, a greater precision could be achieved. Further, the courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not

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function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. v. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987).

Regarding **claim 11**, paragraph [0034] of Kriz discloses using calibration to control the stop position of the piston which reads on the “stroke length” as claimed in that the distance from the start position to the calculated stop position is the stroke length.

Regarding **claim 12**, figures 1 and 2 both show a motor in the system for controlling the piston (paragraphs [0019] and [0046]). Further, the method disclosed in the background of the invention discusses correction of the stroke length of the piston based on the calibration settings.

Regarding **claim 13**, paragraph [0024] of Kriz describes an Adjust function in which the volume desired for dosing is selected.

Regarding **claim 14**, paragraph [0034] describes the calibration technique as involving multiple aspirations of the pipette and calibrating based on the actual quantity of fluid, thus reading on the at least two indicated volumes.

Regarding **claim 15**, Kriz discloses the invention in its entirety but does not explicitly mention calibration calculation with the real volume linearly dependent on the set volume. The background of the present invention states that “calibration is generally performed assuming that the set volume and the dosing volume are linearly

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interdependent" or dependent on one another. It would have been obvious to one of ordinary skill in the art at the time of invention to use the same calibration method as disclosed since it was a well known method at the time of invention for yielding accurate results.

Regarding **claim 16**, paragraph [0010] of Kriz describes the use of a processor and memory for storing presets for piston stop positions and volume compensation algorithms. Paragraph [0035] further describes the preset volumes which can be loaded into the memory of the processor. Since the various volume measurement settings are stored in the memory to save time in changing settings, it would have been obvious to one of ordinary skill in the art at the time of invention to store calibration settings as well in a similar manner for the same reasons. Storing such data in "parallel" as claimed would allow for each piece of data to be accessed independently of the others depending on the volume which is being measured.

Regarding **claim 17**, Kriz discloses a hand-held pipette comprising a calibration system. Figure 2 shows a block diagram of the system comprising a controller 46 ("control system"), a "user interface" 32, and an electronic display 35 in which volumes are shown. The system comprises a motor driven piston for controlling aspiration or dispensing of the pipette (paragraph [0019] and figures 1 and 2). The pipette further comprises a method of calibration of the system which is described in detail in paragraphs [0025]-[0032]. During calibration, a "real volume obtained with an indicated volume" is input to the system and is adjusted to the desired target. The volume is then

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measured by the system and a calibration factor is set based on the input values. The process of calibration is used for future readings, thus the calibration factor would be stored in the memory of the system as claimed. Paragraph [0033] describes the adjustment of the piston/motor assembly during the calibration process to correct for the error in the readings of the pipette, thus corresponding to the real dosing volume. The apparatus of Kriz does not explicitly disclose a calibration resolution of less than 0.05%, however, as the structural limitations of the claim are met by the Kriz reference, the reference reads on the claim. It is noted however that as the calibration resolution is a function of the maximum dosing volume of the pipette, by enlarging the capacity of the pipette, a greater precision could be achieved. Further, the courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. v. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987).

The background of the invention as admitted by the applicant discloses a method of dual point calibration in which input corresponding to real volumes obtained with two volume settings ("real volumes obtained with at least two indicated volumes") is entered into the system and the control system calculates and changes the value of the two constants in a calibration formula ("calibration settings") based on this real volume.

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These calibration settings would be stored in a memory in order to be used effectively and the "stroke length or volume indicated on the display" is set so that the dosed volume equals the indicated with maximum accuracy. It would have been obvious to one of ordinary skill in the art at the time of invention to combine the method of calibration as disclosed by the applicant in the background with the method of Kriz in order to calibrate the pipette with maximal accuracy. The method as admitted discloses the use of calibration on a pipette with a volume of 200 micro liters in which the precision is set to 0.2 micro liters. However it would have been obvious to one of ordinary skill in the art at the time of invention to use the method on any size pipette with a similar precision which could generate much smaller resolutions as the volume increased (i.e. 1000 micro liters with 0.2 micro liter precision would yield a resolution of 0.02%). Further, the specification of the present application does not disclose how a resolution of 0.1%, 0.05% or 0.01% is achieved over the prior art methods. It was known in the art that the greater precision due to a reduced error is beneficial in returning accurate and reliable results, therefore merely indicating that a lower resolution is desired is would have been obvious to one of ordinary skill in the art at the time of invention.

Regarding **claim 18**, Kriz discloses a hand-held pipette and method for operation, including a calibration system. Figure 2 shows a block diagram of the system comprising a controller 46 ("control system"), a "user interface" 32, and an electronic display 35 in which volumes are shown. The system comprises a motor driven piston

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for controlling the volume of liquid aspirated or dispensed from the pipette (paragraph [0019] and figures 1 and 2). The pipette further comprises a method of calibration of the system which is described in detail in paragraphs [0025]-[0032]. During calibration, a "real volume obtained with an indicated volume" is input to the system and is adjusted to the desired target. The volume is then measured by the system and a calibration factor is set based on the input values. The process of calibration is used for future readings, thus the calibration factor would be stored in the memory of the system as claimed. Paragraph [0033] describes the adjustment of the piston/motor assembly during the calibration process to correct for the error in the readings of the pipette, thus corresponding to the real dosing volume. The specification of the present application does not disclose how a resolution of 0.1%, 0.05% or 0.01% is achieved over the prior art methods. It was known in the art that the greater precision due to a reduced error is beneficial in returning accurate and reliable results, therefore merely indicating that a lower resolution is desired is would have been obvious to one of ordinary skill in the art at the time of invention. Additionally, as the resolution is defined as being a function of the measured volume and maximum dosing volume of the pipette, by increasing the dosing volume, a calibration resolution of 0.1% could easily be attained.

Paragraph [0010] of Kriz describes the use of a processor and memory for storing presets for piston stop positions and volume compensation algorithms. Paragraph [0035] further describes the preset volumes which can be loaded into the memory of the processor. Since the various volume measurement settings are stored in the memory to save time in changing settings, it would have been obvious to one of

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ordinary skill in the art at the time of invention to store calibration settings as well in a similar manner for the same reasons. Storing such data in "parallel" as claimed would allow for each piece of data to be accessed independently of the others depending on the volume which is being measured.

Regarding **claim 19**, as with claim 10, the apparatus of Kriz does not explicitly disclose a calibration resolution of less than 0.01%, however, as the structural limitations of the claim are met by the Kriz reference, the reference reads on the claim.

Regarding **claim 20**, the background of the invention as admitted by the applicant discloses a method of dual point calibration in which input corresponding to real volumes obtained with two volume settings ("real volumes obtained with at least two indicated volumes") is entered into the system and the control system calculates and changes the value of the two constants in a calibration formula ("calibration settings") based on this real volume.

Regarding **claim 21**, Kriz discloses a hand-held pipette comprising a calibration system. Figure 2 shows a block diagram of the system comprising a controller 46 ("control system"), a "user interface" 32, and an electronic display 35 in which volumes are shown. The system comprises a motor driven piston for controlling aspiration or dispensing of the pipette (paragraph [0019] and figures 1 and 2). The pipette further comprises a method of calibration of the system which is described in detail in paragraphs [0025]-[0032]. During calibration, a "real volume obtained with an indicated

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volume" is input to the system and is adjusted to the desired target. The volume is then measured by the system and a calibration factor is set based on the input values. The process of calibration is used for future readings, thus the calibration factor would be stored in the memory of the system as claimed. The apparatus of Kriz does not explicitly disclose a calibration resolution of less than 0.1%, however, as the structural limitations of the claim are met by the Kriz reference, the reference reads on the claim. Further, the courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. v. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987).

The background of the invention as admitted by the applicant discloses a method of "single point" calibration in which an input corresponding to a real volume is entered into the system and the control system calculates and changes the value of the correction coefficient ("calibration settings") based on this real volume. These calibration settings would be stored in a memory in order to be used effectively and the "stroke length or volume indicated on the display" is set so that the dosed volume equals the indicated with maximum accuracy. It is also noted that the set volume and the dosing volume are linearly interdependent as claimed and the angular coefficient of the linear equation is present in the equation provided. The method as admitted

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discloses the use of calibration on a pipette with a volume of 200 micro liters in which the precision is set to 0.2 micro liters yielding a resolution of 0.1%. It would have been obvious to one of ordinary skill in the art at the time of invention to combine the method of calibration as disclosed by the applicant in the background with the method of Kriz in order to calibrate the pipette with maximal accuracy.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARK SHABMAN whose telephone number is (571)270-3263. The examiner can normally be reached on M-F 8:00am - 4:30pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/M. S./

Examiner, Art Unit 2856

/Hezron Williams/

Supervisory Patent Examiner, Art Unit 2856